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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,581	08/28/2001	Heiko Hermeking	01107.00187	3865

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EXAMINER	
LOEB, BRONWEN	
ART UNIT	PAPER NUMBER
1636	8

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/939,581	HERMEKING ET AL.	
	Examin r	Art Unit	
	Bronwen M. Loeb	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6-24 and 49-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2,6-24 and 49-83* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This action is in response to the preliminary amendment filed 28 August 2001 in which claims 3-5 and 25-48 were cancelled.

Claims 1, 2, 6-24 and 49-83 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. §121:

   I. Claims 1 and 68, drawn to a purified polypeptide and a method of using it to suppress tumor cell growth, classified in class 530, subclass 350 and class 514, subclass 2, respectively.

   II. Claims 2 and 64-67, drawn to a method of using a polynucleotide encoding 14-3-3σ (SEQ ID No. 2) to suppress tumor growth, classified in class 514, subclass 44.

   III. Claims 6 and 7, drawn to methods of diagnosing cancer using an antibody, classified in class 435, subclass 7.1.

   IV. Claims 6 and 8, drawn to methods of diagnosing cancer using mRNA hybridization, classified in class 435, subclass 6.

   V. Claims 52-63, drawn to an isolated genomic polynucleotide comprising 20 contiguous nucleotides of a 14-3-3σ transcription regulatory region, classified in class 536, subclass 24.1.

VI. Claims 14-23, drawn to antisense nucleic acids and a method of promoting cellular proliferation by inhibiting gene expression, classified in class 536, subclass 24.5.

VII. Claim 24, drawn to a method for assessing susceptibility to cancers, classified in class 435, subclass 6

VIII. Claims 49-51, drawn to a method of identifying a chromosome by nucleic acid hybridization, classified in class 435, subclass 6.

IX. Claims 11-13 and 69-83, drawn to a method for detecting p53, or its activity, in a cell using a 14-3-3σ reporter construct comprising a 14-3-3σ transcription regulatory region, and the construct, classified in class 435, subclass 7.1.

Claim 6 is generic to groups III and IV. If either of these groups is elected, claim 6 will be examined to the extent that it is encompassed by the elected group.

2. The inventions are distinct, each from the other because of the following reasons: The inventions are distinct, each from the other because of the following reasons:

Inventions I, V and VI are distinct products from each other, having different chemical, biological, structural and functional distinctness from each other, and are not disclosed for use together. The protein of group I is chemically and biologically different from the products of groups V and VI and is not required to use the products of groups V and VI. The product of group V is structurally and functionally distinct from the product of group VI and is not disclosed for use with the product of group VI.

Inventions II-IV and VII-IX are distinct methods from each other, having different starting material, different outcomes and different uses. In the instant case, the methods have different purposes which require different method steps. The method of group II requires administering to tumor cells a DNA molecule of SEQ ID No. 1. The method of group III requires the use of an antibody which must bind to a specific protein, and results in the quantification of the protein. The method of group IV requires the use of a nucleic acid which binds to an mRNA, and results in the quantification of the mRNA. The method of group VII requires testing a tissue selected from the group consisting of blood, chorionic villi, amniotic fluid and a blastomere for a mutant 14-3-3σ gene. The method of group VIII requires the step of hybridizing a polynucleotide probe to one or more chromosomes. The method of group IX requires measuring the production of an assayable product in a human tissue in order to detect wild-type p53. Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions VI and IV, VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of group VI can be used in materially different processes, as evidenced by the different methods claimed that could use the product of group VI.

Inventions I and II-IV and VII-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the product of group I is not disclosed as being capable of use in the methods of groups II-IV and VII-IX.

Inventions V and II-IV and VII-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the product of group V is not disclosed as being capable of use in the methods of groups II-IV and VII-IX.

Inventions VI and II, III and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the product of group VI is not disclosed as being capable of use in the methods of groups II, III and IX.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the different, non-coextensive non-patent literature search required for each one, restriction for examination purposes as indicated is proper.

4. A telephone call was made to Sarah Kagan on 2 July 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 11:00 AM to 7:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

February 7, 2003

TERRY MCKELVEY
PRIMARY EXAMINER